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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,959	11/27/2001	Eric Grouzmann	81985/282428	9007
7590 05/04/2004				
MICHAEL A SANZO FITCH EVEN TABIN & FLANNERY 1801 K STREET N W SUITE 401L WASHINGTON, DC 20006-1201			EXAMINER MELLER, MICHAEL V	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,959	GROUZMANN ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-11 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

The election of species of record is maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 9-11, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilkinson et al. (col. 3, line 38-44, col. 9, line 20-42), Houston (col. 3, line 4-20, col. 8, line 34-46), Robison (col. 10, line 16-22, col. 59, line 12-15) or Petell et al. (col. 5, line 10-24, col. 12, line 54-60).

Applicant argues that Petell is concerned with monoclonal antibodies that bind to membrane proteins found on insect cells. While this is noted, the reference also teaches that DPPIV (dipeptidyl peptidase IV-the elected enzyme) can be used in an aerosol form. Such aerosol form would read on the claims since the claims are not directed to use but only a device containing the enzyme.

Applicant next argues that Robinson teaches a large scale sequencing study which a large variety of protease families were identified using sequence homology

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data. While this is noted, it is not well taken because again, the art recognizes that DPPIV can be administered by inhalation, i.e. aerosol spray.

Houston is argued by applicant as teaching with the treatment of patients for autism. Once again, the claims are directed to a device not a method of using the device. Houston very clearly teaches that DPPIV can be administered nasally.

Wilkinson is argued by applicants as concerned with reducing opioid-related symptoms. Once again, the DPPIV is noted as being administered nasally.

Applicant argues that the enzymes and methods of administration are chosen from a long list of option and that oral administration is preferred in some of the patents. This is not well taken since the DPPIV is clearly contemplated in each patent and there is only one enzyme, namely DPPIV to be claimed not a list of them. One of ordinary skill in the art could easily see that any of these enzymes would work in the disclosed method of the patents. The patents also teach that intranasal administration is taught. Once again, intranasal administration is taught and it is well within the purview of the skilled artisan to use one of the methods disclosed. This rejection is under 35 USC 103 for a reason, namely that one of ordinary skill in the art would have been motivated to use any of the routes of administration disclosed since they all are known to work in the disclosed patents. One of ordinary skill in the art has no reason to believe that nasal administration does not work. Simply because some of the patent make show oral as preferred does not negate the fact that they clearly contemplate nasal administration as claimed.

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This is an RCE of applicant's earlier Application No. 09/993,959. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM
4/22/2004